



CryoPRO Workstation

USER MANUAL

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It is strongly recommended that all users read this manual in its entirety before using the CryoPRO Workstation.

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Section 1: Introduction

The CryoPRO Workstation is a piece of manufacturing equipment intended to simplify the operation of the CryoPRO-2 Cryopreservation/Storage Bag Set, or its equivalent. It also provides convenient mixing for the transfer of the buffy coat from the SynGenX™-1000 System Disposable Cartridge, or its equivalent.

While the CryoPRO-2 Cryopreservation/Storage Bag Set and the Disposable Cartridge may be operated without the use of the CryoPRO Workstation, the CryoPRO Workstation does provide the functions of mixing, cooling and addition of the cryoprotectant in one unitary work station. This minimizes the need for multiple power cords, crisscrossing tubing lines, and widely separated operating controls for each individual unit.

The CryoPRO Workstation comes programmed from the manufacturer with a 2 minute mixing motion for the Disposable Cartridge, a cryoprotectant dispensing syringe pump that flows at a rate of 5 mL in 15 minutes, and an orbital cooling mixer that maintains the buffy coat between 4 and 6 °C.

The CryoPRO Workstation is capable of a range of a 10 second to 20 minute mixing motion for the Disposable Cartridge, a cryoprotectant dispensing syringe pump that can flow at a maximum rate of 5 mL in 1 minute, and an orbital cooling mixer that can maintain the buffy coat between 1 and 15 °C.

If desired for other applications, these operating values, either singly or in combination, can be supplied directly from SynGen, Inc. They may also be field re-programmed by the operator using a standard digital interface and off-the-shelf software. Contact SynGen for re-programming interface and instructions.









The CryoPRO Workstation is intended to be used under routine laboratory conditions.

Overview

In addition to simplifying the use of CryoPRO Cryopreservation/Storage Bag Set and the Disposable Cartridge, the CryoPRO Workstation is designed to provide process consistency and electronic documentation of buffy coat cryoprotection. It simplifies:

- Buffy coat transfer from the SynGenX-1000 Disposable Cartridge to the CryoPRO-2 Cryopreservation/Storage Bag Mixing Chamber
- Temperature control of the buffy coat during cryoprotectant transfer
- Precise flow rate control of the cryoprotectant solution
- Storage bag compression to aid in air removal from the storage bag
- Transfer of the cryoprotected buffy coat to the storage bag
- Mechanical verification of storage bag fill volume for fit into freezing cassettes

Symbol Key

Symbol	Description
	Power Off
	Power On
	Do not trash as municipal waste
	Authorized Representative for European Union
	Manufactured By
	Warning to be observed by the user
	Precaution to be observed by the user
	A note to be observed by the user

Abbreviations

Abbreviation	Definition
IEC	Internal Electro Technical Commission
LED	Light Emitting Diode
ME	Manufacturer's Equipment
P/N	Part Number
RF	Radio Frequency
RoHS	Restrictions on the use of certain hazardous substances
S/N	Serial Number

Section 2: Safety

Warnings



A warning is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

- Read the CryoPRO Workstation User Manual prior to using the device.
- Always follow established laboratory procedures for handling and disposing biohazardous materials.

Precautions



A precaution is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property. The caution statement includes the **precaution** that should be taken to avoid the hazard.

- The CryoPRO Workstation contains modules with moving parts. Avoid placing any foreign object near or into the moving components as damage may occur.
- Do not allow fluid to enter into the CryoPRO Workstation. In the event of a spill, turn the power switch off and clean the spill as quickly as feasible following established laboratory procedures. Contact SynGen customer support at 1.844.363.0709 or 1.916.256.2423 (outside of the USA) or by email at support@syngeninc.com for further action.
- Immediately replace the Thermal Insert once the Mixing Chamber has been removed after processing to prevent moisture build up within the Mixing Thermoelectric Cooling Module.

Safety and EMC Compliance Information

Safety Standards

Regulations and recommendations contained in this document are in compliance with appropriate international safety standards. This includes electrical instruments used in laboratory, protection of laboratory staff, and electrical safety.

Table A – Guidance and manufacturer’s declaration – Electromagnetic Emission for all Equipment and Systems


Guidance and manufacturer’s declaration – electromagnetic emissions for all ME EQUIPMENT and ME Systems		
The CryoPRO Workstation is intended for use in the electromagnetic environment specified below. The customer or the user of the CryoPRO Workstation should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The CryoPRO Workstation uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CryoPRO Workstation is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table B – Guidance and manufacturer’s declaration – Electromagnetic Emission for all Equipment and Systems

Guidance and manufacturer’s declaration – electromagnetic immunity for all ME EQUIPMENT and ME SYSTEMS			
The CryoPRO Workstation is intended for use in the electromagnetic environment specified below. The customer or the user of the CryoPRO Workstation should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CryoPRO Workstation requires continued operation during power mains interruptions, it is recommended that the CryoPRO Workstation be powered from an uninterruptible power supply or a battery.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: <i>UT</i> is the A.C. mains voltage prior to application of the test level.			

Table C - Guidance and manufacturer's declaration – Electromagnetic Immunity for EQUIPMENT and SYSTEM that are not LIFE SUPPORTING

The CryoPRO Workstation is intended for use in the electromagnetic environment specified below. The customer or the user of the CryoPRO Workstation should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the CryoPRO Workstation, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	<p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CryoPRO Workstation is used exceeds the applicable RF compliance level above, the CryoPRO Workstation should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CryoPRO Workstation.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Section 3: CryoPRO Workstation Description

The following section provides a description of the CryoPRO Workstation components.

CryoPRO Workstation Front Panel

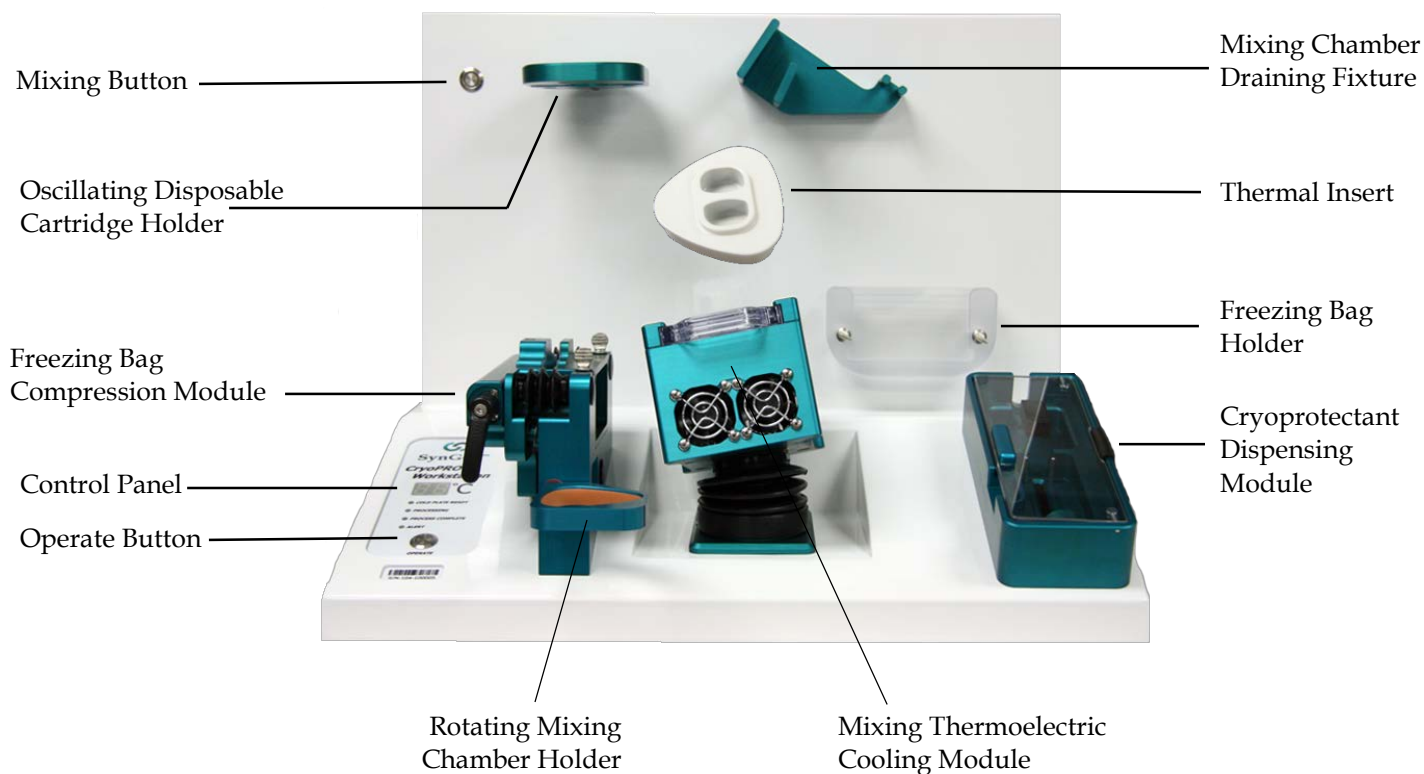


Figure 1: CryoPRO Workstation Front

Mixing button: A button to activate the mixing and transfer of the buffy coat from the Disposable Cartridge to the mixing chamber. The Mixing button is illuminated when waiting to start the mixing cycle and unlit during the mixing cycle.

Oscillating Disposable Cartridge Holder: Designed to hold and oscillate the Disposable Cartridge during buffy coat transfer from the Disposable Cartridge to the CryoPRO-2 Cryopreservation/Storage Bag mixing chamber.

Freezing Bag Compression Module: Holds the freezing bag upright and in place. A rotating lever compresses the bag and eliminates the air.

Control Panel: Provides status light and temperature indicators during CryoPRO Workstation operation.

Operate Button: The Operate Button initiates the cryoprotectant addition process. The button is illuminated when waiting to start, at the end of the process, and unlit during the process. If an

error occurs the button will illuminate and be accompanied by an audible beeping sound. Pressing the Operate Button will stop the audible beeping sound.

Rotating Mixing Chamber Holder: A holder designed to hold the mixing chamber during buffy coat transfer and rotate the mixing chamber for optimal sample collection.

Mixing Thermoelectric Cooling Module: The module monitors and controls the temperature of the buffy coat during cryoprotectant addition and provides orbital mixing throughout the process.

Cryoprotectant Dispensing Module: Provides a controlled rate of cryoprotectant infusion. It includes a spring activated door latch, syringe holder with placement pins, and dispensing base.

Freezing Bag Holder: A clear plastic holder designed to mechanically set the volume for the two freezing bag chambers.

Thermal Insert: An insert in the shape of the mixing chamber that is in place within the Mixing Thermoelectric Cooling Module when the module is not in use.

Mixing Chamber Drainage Fixture: A fixture designed to orient the mixing chamber for optimal drainage of the cryoprotected cells into the freezing bag.

CryoPRO Workstation Lower Back Panel

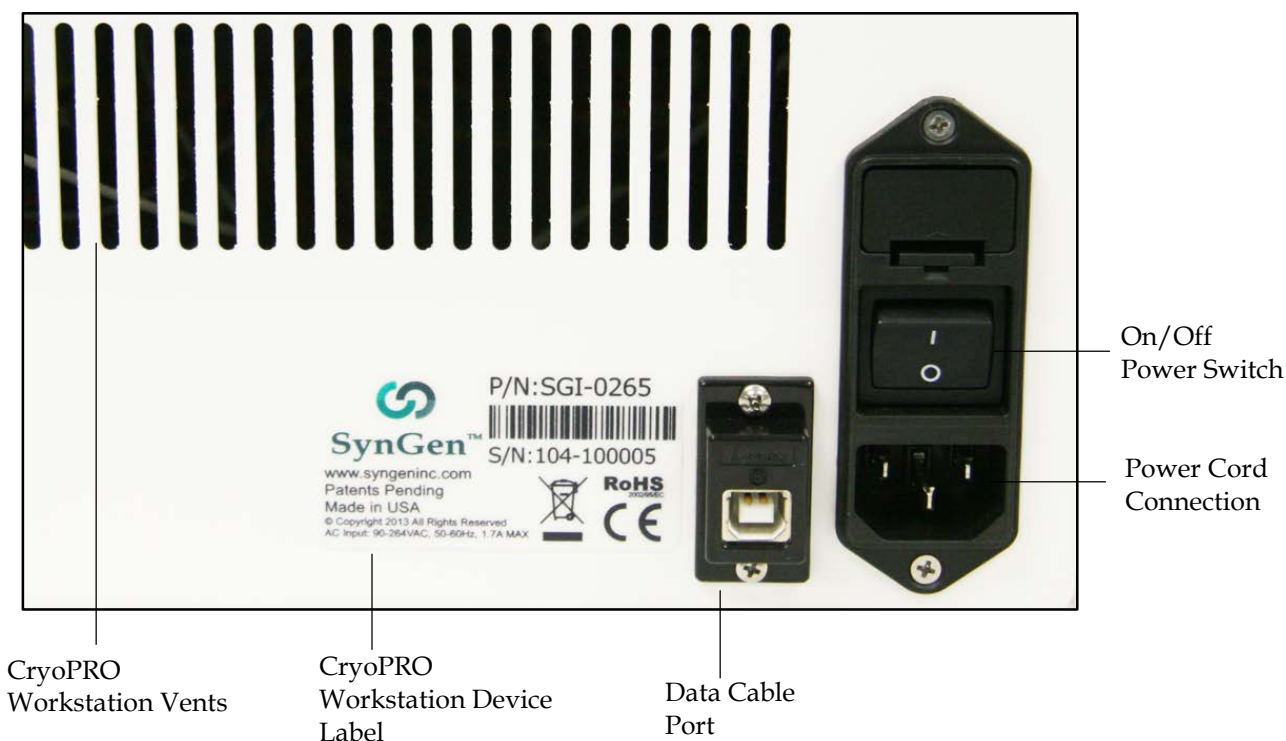


Figure 2: CryoPRO Workstation Lower Back Panel

CryoPRO Workstation Vents: Exhaust vents for the CryoPRO Workstation electrical and mechanical components.

CryoPRO Workstation Device Label: Provides information specific to the CryoPRO Workstation.

Data Cable Port: Port for data connection to the host PC via a data cable.

Power Cord Connection: Connection for power cord.

On/Off Power Switch: Power switch for the CryoPRO Workstation. Press to turn on (I) or off (O).

CryoPRO Workstation Control Panel

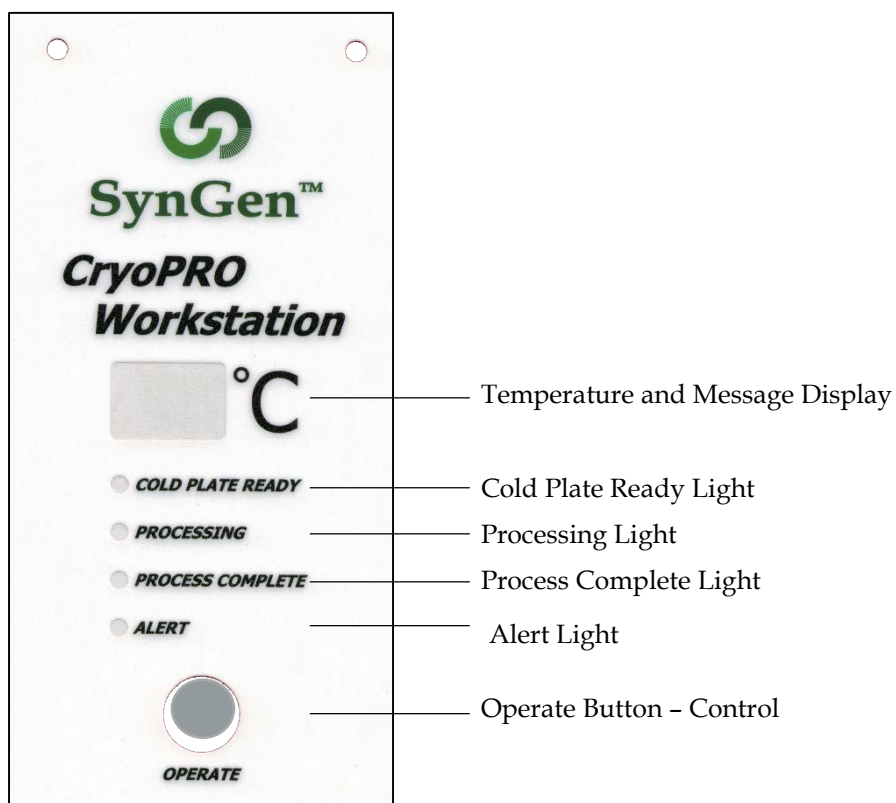


Figure 3: CryoPRO Workstation Control Panel

Temperature and Message Display: Displays the temperature in degrees Celsius and non-numeric status and error codes. The status messages are indicated below. Refer to the Troubleshooting Section for Error Codes and additional information.

Status Display	Status Description
--	Waiting to process
dP	Data present and available for download

Cold Plate Ready Light: Illuminates when the temperature of the Mixing Thermoelectric Cooling module is within the specified temperature range.

Processing Light: Illuminates during the cryoprotectant addition process.

Process Complete Light: Illuminates at the completion of the cryoprotectant addition process.

Alert Light: Illuminates either a red or yellow LED. A yellow LED corresponds to error that occurred during the cryoprotectant addition process. The associated error code is displayed on the Sample Temperature Display. A red LED indicates that there is a hardware fault in the CryoPRO Workstation.

Operate Button: The Operate Button initiates the cryoprotectant addition process. The button is illuminated when waiting to start, at the end of the process, and unlit during the process. If an error occurs the button will illuminate and be accompanied by an audible beeping sound. Pressing the Operate Button will stop the audible beeping sound.

Section 4: CryoPRO Workstation Installation



Operators should be trained on the SynGenX™-1000 System before setting up and operating the CryoPRO Workstation.

The CryoPRO Workstation transfers processing data to the SynGen™ DataTrak Software. The data from each processing run must be downloaded to the software before a next processing run can be conducted. Prior to setting up the CryoPRO Workstation ensure the host computer has the DataTrak Software installed and the CryoPRO Workstation has been registered in the software. Refer to the SynGenX™-1000 System User Manual Operating Instructions, DataTrak Software, for registering the CryoPRO Workstation.

The CryoPRO Workstation comes fully assembled and includes the power cord and data cable. Carefully unpack the workstation and verify all components are present and undamaged. Contact SynGen Customer Service at **1.844.363.0709** or **1.916.256.2423** (outside of the USA) or by email at **support@syngeninc.com** if any component is missing or any parts are damaged.

1. Ensure the Thermal Insert is in place. The Thermal Insert must be in place when the CryoPRO Workstation is not in use.
2. Ensure the door to the Mixing Thermoelectric Cooling Module is closed.
3. Rotate the Rotating Mixing Chamber Holder to the horizontal position.
4. Attach the power cord to the back of the device.
5. Attach the data cable to the data cable port and to the USB hub port connected to computer or directly to the computer as applicable.
6. Plug in the power cord to power source.
7. Press the power switch to the ON position.
8. The CryoPRO workstation Mixing Button will illuminate and the Mixing Thermoelectric Cooling Module will rotate and home.
9. The CryoPRO Workstation is ready for processing once the Cool Plate Ready Light and the Control Panel Operate Button are illuminated.
10. Register the CryoPRO Workstation into the SynGen DataTrak software as per instructions for use found in the SynGenX™-1000 System User Manual.

Section 5: CryoPRO Workstation Operating Instructions

Provided Equipment

- CryoPRO Workstation with power and data cables

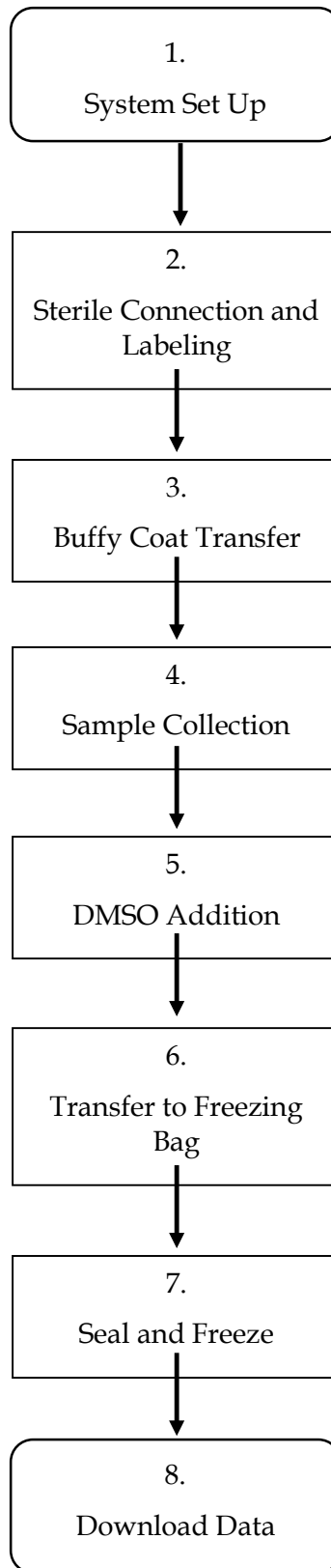
Equipment, Materials, and Reagents required but not provided

- CryoPRO Workstation
- Tubing Welder
- Tube Sealer(s) for PVC and EVA tubing
- Barcode Label Generator(s) for freezing bag, cassette, and sample tubes
- Computer with SynGen DataTrak Software installed
- Cryogenic Freezer
- SynGenX™-1000 Disposable Cartridge with processed cord blood
- CryoPRO-2 Cryopreservation/Storage Bag Set
- 10mL BD Luer-lok™ Syringe
- Tubing slide clamps or Hemostats
- Freezing bag labels
- Sample bulb and sample tube labels
- DMSO/Dextran Solution (55% dimethyl sulfoxide with 5% Dextran 40 solution)

Equipment recommend but not provided

- 2.0 USB Hub
 - For Windows® 7 Operating Systems, only USB 2.0 Ports on the computer are compatible with the DataTrak software
- Barcode Scanner

Process Flow



Operating Instructions

System Set Up

1. Press the power button to the ON position on the rear left of the CryoPRO Workstation. The workstation should remain on until all processing for the day is complete.
2. Verify that the Thermal Insert is in place within the Mixing Thermoelectric Cooling Module. The Thermal Insert must be left in place when not in use.
3. Verify that the door to the Mixing Thermoelectric Cooling Module is closed.
4. Verify that the Rotating Mixing Chamber Holder is set to a horizontal position.
5. Verify the symbol “- -” is displayed on the Control Panel.
6. Obtain and remove the CryoPRO-2 Cryopreservation/Storage Bag Set and extension tube from its packaging.
7. Clamp input tubing near the Air Filter on the CryoPRO-2 Cryopreservation/Storage Bag Set.
8. Aseptically fill the 10mL BD Luer-lok™ syringe with at least 6.2 mL of DMSO/Dextran solution. Eliminate any extra air that may be present in the syringe as it may impact the total volume delivered.
9. Remove cap from extension tubing and aseptically attach to the solution filled syringe.
10. Store syringe and extension tubing in refrigerator until needed for cryoprotectant addition.

Sterile Connection and Labeling

1. Ensure the SynGenX™-1000 Control Module processing data has been downloaded to the DataTrak Software before proceeding with the buffy coat transfer to the CryoPRO-2 Cryopreservation/Storage Bag Set.
2. Identify the buffy coat sample access tubing opposite of the SynGenX™-1000 Disposable Cartridge label and pull the tubing from the clamps. Squeeze the tubing where it was clamped to ensure the tubing is fully open.



Figure 4: Buffy Coat Sample Access Tube identified and squeezed

3. Sterile connect the Disposable Cartridge buffy coat sample access tubing to the input tubing on the CryoPRO-2 Cryopreservation/Storage Bag Set as per manufacturer's instructions for use. The tubing length between the Disposable Cartridge and the Air Filter should be approximately 14 ± 1 inches to facilitate lean process flow and allow mixing chamber to be seated in the Rotating Mixing Chamber Holder.
4. Label the Freezing Bag and Sampling Bulb of the CryoPRO-2 Cryopreservation/Storage Bag Set. Ensure labels are in place before removing from the sterile connection device.

Buffy Coat Transfer

1. Remove the Disposable Cartridge from the Control Module by squeezing both locking tabs and lifting straight up.



Figure 5: Disposable Cartridge removed from Control Module

2. Place the Disposable Cartridge in the Oscillating Disposable Cartridge Holder of the CryoPRO Workstation so that the label is facing to the right (locking tabs will be parallel to the back of the Workstation). Squeeze the locking tabs and then set onto the stand. Release the tabs and ensure the Disposable Cartridge is latched into place.

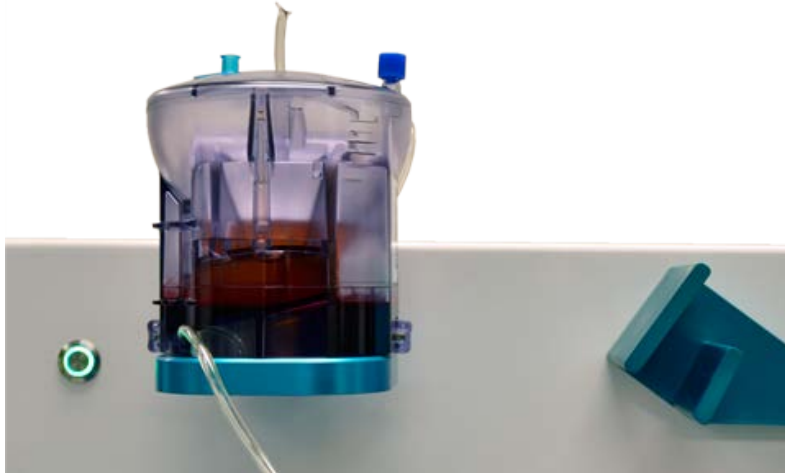


Figure 6: Disposable Cartridge latched onto the Oscillating Disposable Cartridge Holder

3. Place the Mixing Chamber into the Rotating Mixing Chamber Holder so that the DMSO Filter is away from you (12 o'clock).



Figure 7: Mixing Chamber in Rotating Mixing Chamber Holder with DMSO Filter at 12 o'clock

4. Remove and retain the cap from the DMSO filter and open the clamp on the sterile connection tubing.
5. Allow the buffy coat to drain until it is approximately half empty. The fluid level should be level with the seam.



Fluid level at seam

Figure 8: Fluid level drained half way and level with the seam

6. Clamp the tubing and then press the Mixing Button.
7. Once the mixing has stopped, remove the clamp and allow all of the buffy coat to transfer to the Mixing Chamber.
8. Clamp tubing between the Y connector and the Air Filter.
9. Replace cap on DMSO filter.

Sample Collection

1. Rotate the Rotating Mixing Chamber Holder to the vertical position.

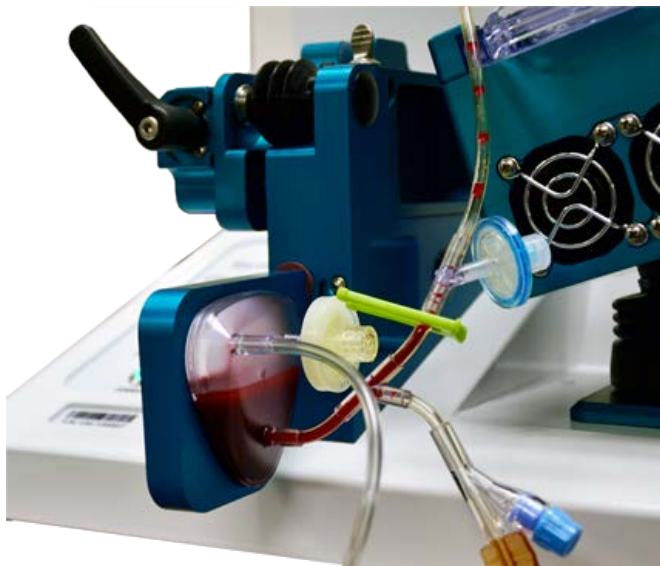


Figure 9: Mixing Chamber rotated to the vertical position

2. Squeeze the Sampling Bulb approximately 10 times to thoroughly mix the buffy coat.

3. Return the Rotating Mixing Chamber Holder to the horizontal position. Squeeze the Sampling Bulb to obtain the appropriate sample volume and then remove any blood from the line with air from the Sampling Bulb.

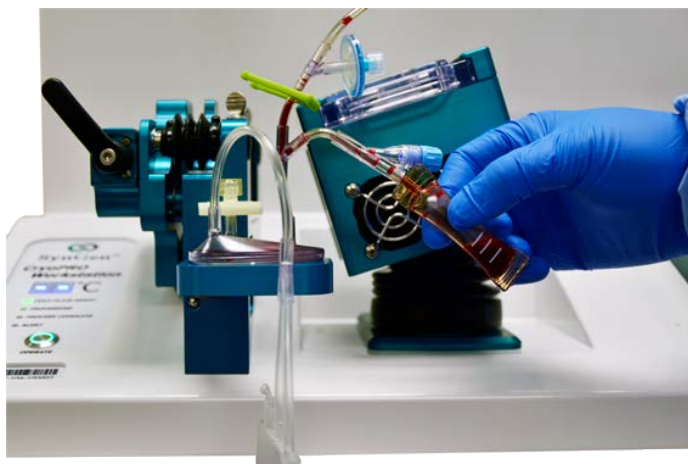


Figure 10: Sample collection

4. Seal the tubing leading to the Sampling Bulb and the tubing directly above the Air Filter.
5. Detach Sampling Bulb and Disposable Cartridge.
6. Access sample from Sampling Bulb via the needleless access port and transfer to tubes per established procedures.
7. If desired for other purposes, the RBCs within Disposable Cartridge may be accessed by syringe via the sample access tube near the Disposable Cartridge label and plasma may be accessed by syringe via the Central Funnel Compartment access port at the top of the Disposable Cartridge.

Cryoprotectant Addition

1. Verify that the Cold Plate Ready Light on the Control Panel is illuminated.



Figure 11: Cold Plate Ready light illuminated

2. Obtain the cryoprotectant solution filled syringe. Remove the cap from the DMSO Filter and extension tubing and connect the tubing to the DMSO Filter.
3. Slide the Mixing Thermoelectric Cooling Module door open and remove the Thermal Insert.
4. Keep the Mixing Chamber upright, then place it into the Mixing Thermoelectric Cooling Module so that the DMSO filter is away from you (1 o'clock). The Freezing Bag will be positioned left toward the Freezing Bag Compression Module. Slide the door closed.

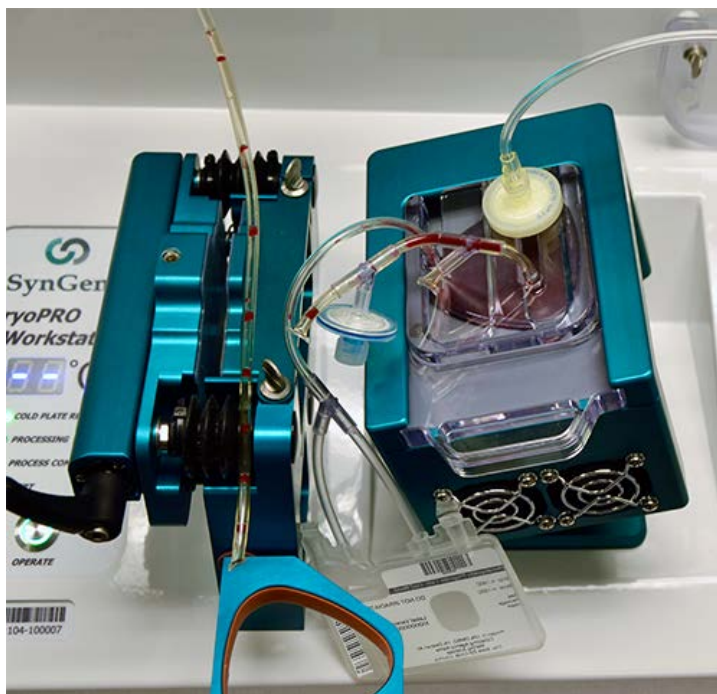


Figure 12: Mixing Chamber placed in the Mixing Thermoelectric Cooling Module with DMSO Filter at 1 o'clock

5. Open the Cryoprotectant Dispensing Module door by pushing on the door which releases the door latch.
6. Load the syringe so that the flange of the syringe is above the retaining pins of the holder and close the door ensuring it latches.

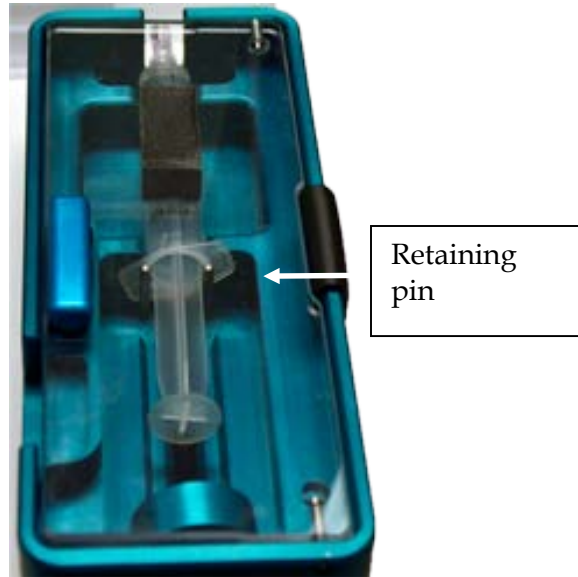


Figure 13: Flanges of syringe above retaining pins

7. Drape the tubing underneath the Freezing Bag Holder.
8. Place the Freezing Bag into the Freezing Bag Compression Module.
9. Remove the cap from the Air Filter and release the clamp below the Air Filter.
10. Promptly press the Control Panel Operate Button to start the Mixing Thermoelectric Cooling Module.
11. Once the appropriate temperature is achieved, the Processing light will illuminate and the Cryoprotectant Dispensing Module will begin the DMSO addition automatically.

Compress Freezing Bag

1. Rotate the handle counter clockwise until it can go no further and the Freezing Bag is fully compressed.

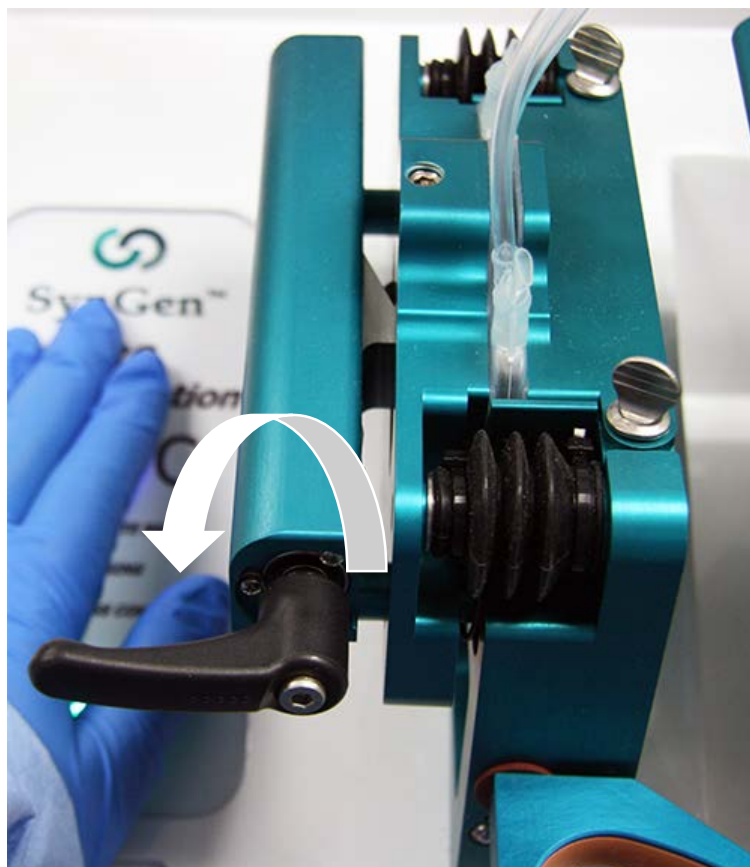


Figure 14: Compressed Freezing Bag

2. Clamp both of the segment tubes leading to the Freezing Bag.
3. Rotate the handle clockwise until it can go no further and the Freezing Bag Compression Module is fully open.

Transfer to Freezing Bag



The following steps should be performed without excessive delay.

1. The DMSO addition process is complete when the Process Complete light illuminates and an alert sounds.



Figure 15: Process Complete light illuminated

2. Press the Control Panel Operate Button to stop the Mixing Thermoelectric Cooling Module.
3. Slide the Mixing Thermoelectric Cooling Module door open and remove the Mixing Chamber.
4. Place the Mixing Chamber in the Mixing Chamber Draining Fixture so that the DMSO Filter is uppermost and toward you.



Figure 16: Mixing Chamber placed within Mixing Chamber Draining Fixture with DMSO Filter uppermost and toward you

5. Place the Air Filter onto the filter retainer on the fixture.

6. Replace the Thermal Insert into the Mixing Thermoelectric Cooling Module and slide the door closed.
7. Remove clamp leading to the small chamber of the Freezing Bag. Buffy coat will fill most of the chamber automatically
8. Completely express air from the small chamber allow it to fill, then clamp tubing leading to small chamber.
9. Remove clamp from tubing leading to large chamber of the Freezing Bag. Buffy coat will fill most of the chamber automatically.
10. Completely express air from the large chamber and allow to it fill until the Mixing Chamber has emptied.
11. Place Freezing Bag into Freezing Bag Holder.
12. Remove clamp, the buffy coat will equilibrate between the two chambers and tubing segments.
13. Ensure segment tubing is completely filled then clamp the tubing just above the Y connector.
14. Seal tubing segments directly below the Y connector then remove clamp.
15. Make segments by sealing the tubing perpendicular to the Freezing Bag.



Figure 17: Freezing Bag with segments prepared.

16. Detach Freezing Bag.
17. Fold segments over top of Freezing Bag to prepare for overwrapping (if applicable) and freezing.
18. Freeze as per manufacturer's instructions for use and established procedures.
19. Discard Mixing Chamber per established procedures.

Download Processing Data

1. Double click on the DataTrak icon located on the PC desktop to launch the software.
2. Enter appropriate User ID and corresponding Password and click on the Submit button.
3. Click on the CryoPRO Workstation picture on the left navigation pane.

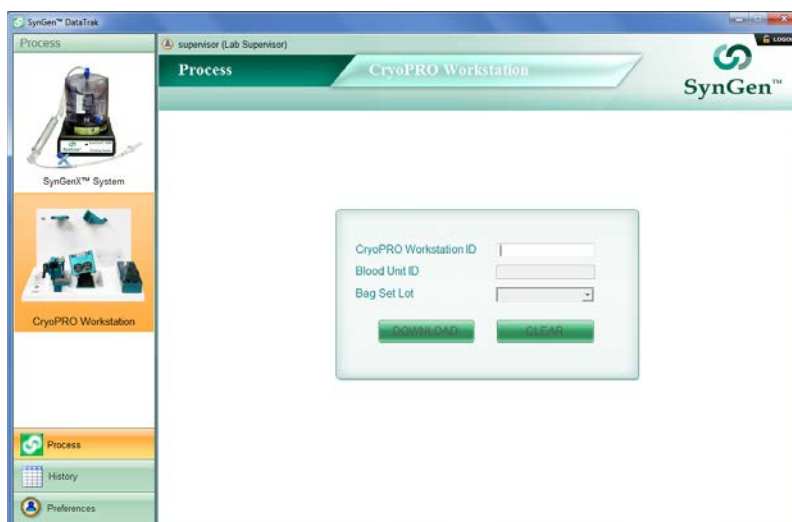


Figure 18: CryoPRO Workstation download window

4. Scan the barcodes in the order indicated below on the download window.
 - a. CryoPRO Workstation ID
 - b. Blood Unit ID
 - c. Bag Set Lot

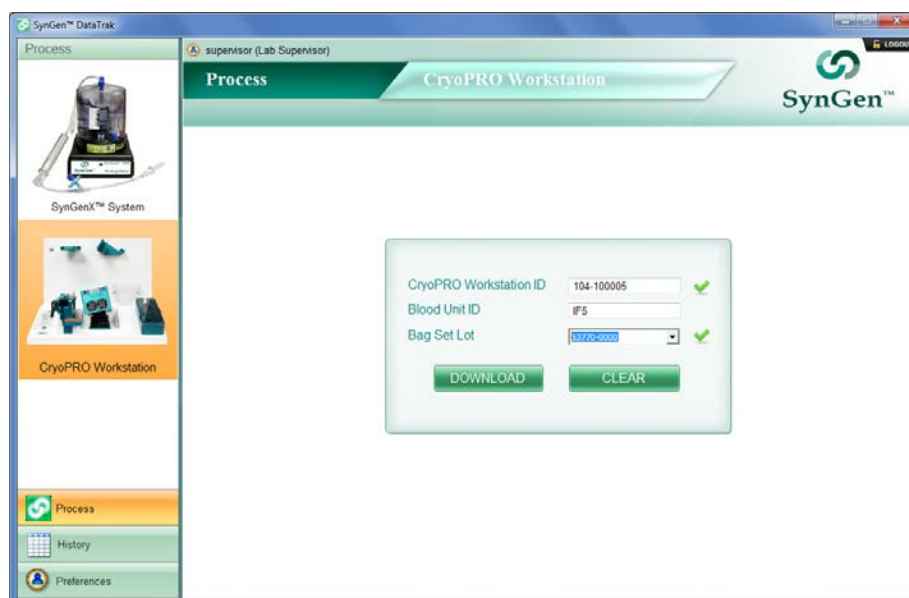


Figure 19: Acceptable entry with green check marks

5. A green check mark will indicate an acceptable entry, a red X will indicate an unacceptable entry. Verify information associated with a red X and re-enter as appropriate.
6. Click on the **Download** button to download the data located on the Control Module.
7. Review report and obtain supervisor approval as indicated.
8. To add a note to the report, move cursor to the field beside User Notes. Enter appropriate information and then click on the **Save User Notes** button.

9. To print the report, click on the **PRINT** button. The print preview window is displayed. Click on File, then Print. Select the appropriate printer and click on the **Print** button.
10. To save the report as a pdf file, click on the **SAVE AS PDF** button. Select the file location and edit the file name if applicable and click on the Save button.
11. To close the file, click on the red X in the upper right window.
12. The report may be printed or saved as a PDF by clicking on the appropriate button.
13. To export the file into Excel® spreadsheet for troubleshooting, click on the **Export** button. Select the file location and edit the file name if applicable.
14. After data transfer the CryoPRO Workstation is ready for subsequent processing, as indicated by the presence of the symbol “- -” on the Control Panel display.

Section 6: Disinfection and Maintenance



Always follow established procedures for handling and discarding biohazardous materials.

Power down the CryoPRO Workstation. Use a dry cloth or paper towel to wipe away any liquid that maybe present. Then, wet a paper towel with a 10% bleach solution or a 70% isopropyl alcohol solution and wipe down all outside surfaces, taking care not to allow any solution to enter directly into the modules or vents. Allow the solution to stay on the surface for 5 minutes then dry with a paper towel.

Besides disinfection, there is no other routine maintenance required. If an error code is experienced, first consult the Troubleshooting Section of this manual. If the problem persists, please contact SynGen, Inc. Customer Service at **1.844.363.0709** or **1.916.256.2423** (outside of the USA) or by email at **support@syngeninc.com**.

Section 7: Customer Service

The CryoPRO Workstation is supplied with a copy of the User Manual. In addition, professional and competent technical staff will provide end-user training prior to its use and will always be available for specific questions or clarifications.

For assistance with technical or application issues, please contact your account representative or SynGen, Inc. Customer Service at **1.844.363.0709** or **1.916.256.2423** (outside of the USA) or by email at **support@syngeninc.com**. Contact hours for SynGen Customer Service are 9:00 to 17:00 Pacific Time. Email submissions will be responded within 1 business day of receipt.

SynGen, Inc.

Sacramento, CA 95818

Email: support@syngeninc.com

Customer Service: at 1.844.363.0709 or 1.916.256.2423 (outside of the USA)

Fax: 1-916-706-0832

Section 8: Troubleshooting

The Troubleshooting section describes the appropriate steps to take in the event that a processing run did not perform as intended. For additional troubleshooting or technical assistance contact SynGen, Inc. Customer Service at **1.844.363.0709** or **1.916.256.2423** (outside of the USA) or by email at **support@syngeninc.com**.

CryoPRO Workstation Alerts and Error Codes

The table below identifies the displayed alerts and error codes for the CryoPRO Workstation and appropriate user actions. All alerts and errors include an audible beep in addition to the LED display.

Displayed Character	Description	Action By User
CF	Mixing Thermoelectric Cooling Module communication failure.	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.
do	Cryoprotectant Dispensing Module door is open during processing.	Close Cryoprotectant Dispensing Module door. Process will automatically resume. If door is left open too long the process will be aborted. Follow internal procedures for cryoprotectant addition time limits.
FE	Problem interacting with flash memory.	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.
FF	Mixing Thermoelectric Cooling Module fans out of range.	Turn off the CryoPRO workstation. Verify the fans are not obstructed and remove if present. Turn on the CryoPRO Workstation. If error repeats, contact SynGen Customer Service and return for service.

Displayed Character	Description	Action By User
HF	Mixing Thermoelectric Cooling Module home failure.	Verify the Mixing Thermoelectric Cooling Module is not obstructed. Turn the CryoPRO Workstation off and then on. If error repeats, contact SynGen Customer Service and return for service.
nF	Mixing Thermoelectric Cooling Module motion failure.	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.
Pd	Mixing Thermoelectric Cooling Module plate temperature delta too large.	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.
PH	Cryoprotectant Dispensing Module home failure.	Open Cryoprotectant Dispensing Module door and verify that there are no obstructions. Turn off the CryoPRO Workstation and then turn back on and restart process. If error repeats, Contact SynGen Customer Service and return for service.
SE	Cryoprotectant Dispensing Module failed to engage the syringe.	Press the operate button to silence the alarm. Open Cryoprotectant Dispensing Module door and verify that the DMSO solution syringe has the proper fill volume and is correctly placed within the compartment. Press the operate button to resume processing. If error repeats, Contact SynGen Customer Service and return for service.

Displayed Character	Description	Action By User
SF	Out of memory.	Turn the off the CryoPRO Workstation and then turn on. Download the processing data. If error repeats, contact SynGen Customer Service and return for service.
SH	Mixing Thermoelectric Cooling Module sample temperature is too high (>10° C).	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.
SL	Mixing Thermoelectric Cooling Module sample temperature too low (<1° C).	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.

Section 9: CryoPRO Workstation Specifications

Feature	Specification
Height	16 inches
Width	20 inches
Depth	15.75 inches
Weight	25 lbs.
AC Line Voltage	100-240 VAC
Frequency	50/60 Hz
Power Consumption	150 Watts
Operating Environment	
Operating Altitude	Up to 6600 feet (2000 meters)
Relative Humidity	30% - 75% non-condensing
Operating Temperature	4 ° - 30° C
Storage Temperature	7° - 50° C

Section 10: Warranty

SynGen, Inc. warrants to original purchaser that the CryoPRO Workstation will be free from defects in material or workmanship for one (1) year from date of shipment.

SynGen also warrants that spare parts will be free from defects in material workmanship for a period of ninety days (90), or maximum time required by applicable local law, from date of shipment of spare part.

SynGen products are designed and manufactured to provide trouble free and reliable performance when properly maintained and used in accordance with the instructions provided in this manual. Each CryoPRO Workstation (referred to as “Device”) is carefully inspected and tested before shipping.

In case of device failure or malfunction, SynGen will replace or repair the concerned device according to the agreement in place.

Device failure or malfunction for reasons other than those caused by defects in materials or manufacturing defect (such as improper handling of the machine, misuse, accident, or non-compliance with the User Manual) is not covered under the SynGen warranty program and such device will be replaced or repaired at the charge of the end-user.

Any alterations or modification made to the device (other than those made by SynGen) will render the warranty null and void. SynGen will not be responsible for any consequential or incidental damages resulting from device malfunction or loss of use of device.

SynGen shall under no circumstances be liable for consequential or economic damage that may be an indirect or direct consequence of a defective part.